

REMARKS

Status of Claims

Claims 1-36 are pending in the application and rejected. Claims 1-36 are rejected. Claims 1 and 3 have been amended. Support for the amendments can be found in the specification as originally filed. See e.g. col. 4, lines 1-3. No new matter has been added.

Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-36 under 35 U.S.C. §103(a) over Edwards et al. '441 ("Edwards I") in view of Edwards '906 ("Edwards II") and further in view of Swanson '760. The Examiner states that regarding independent claims 1 and 3 Edwards I discloses the claimed subject matter but does not disclose that the method is used to reduce bleeding and/or blood loss. The Examiner also states that Edwards I fails to disclose making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing tips along an incision line. The Examiner then states that Edwards II discloses a tissue heating device having retractable needles and teaches the alleged equivalent energy delivery of microwave with cooling means and RF. Lastly, the Examiner states that Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue. Having completed the theoretical combination, the Examiner states that therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards I, as it is known in the art that blood flow in tissue is greatly reduced if tissue is heated 20°-30° C, as further taught by Edwards II, and finally as taught by Swanson, i.e. to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue. Applicant traverses the rejection and respectfully requests reconsideration.

In addressing Applicant's arguments filed on April 5, 2007 the Examiner states that Applicant addressed each reference individually and did not address the references in combination. Applicant respectfully disagrees with the Examiner. In order to address references in combination, one must necessarily discuss what those references teach individually in order to ascertain what they would suggest to one skilled in the art. After a discussion of what each

reference taught, Applicant then discussed the combination suggested by the Examiner. See page 6, paragraph 2 of Response. The Examiner states that the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art citing *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871,881 (CCPA 1981). Applicant agrees. The Examiner also states that a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint of suggestion in a particular reference citing *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). Applicant also agrees. Applicant merely pointed out that under existing case law even if the combination of the references taught every element of a claimed invention the level of skill in the art cannot be relied upon to provide the suggestion to combine references. MPEP §2143.01.

Notwithstanding the foregoing, Applicant respectfully suggests that neither Edwards I, nor Edwards II, nor Swanson '460 alone or in combination make the claimed invention obvious. This is so despite the general knowledge of one skilled in the art that heating tissue reduces blood flow. When a combination of elements yield an unpredictable result, the combination is not obvious. In particular, when prior art references teach away from the combination, the discovery of successful means to combine them is more likely to be nonobvious. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d at 1395.

In additional support of its argument that the invention claimed by independent claims 1 and 3 are not obvious, Applicant submits a Declaration of Commercial Success Under 37 C.F.R. §1.132.

Edwards I teaches the reduction of tissue mass in the vicinity of an electrode that comprises a stylet. The Edwards stylet has a retractable sleeve portion that when retracted exposes only the stylet tip. The sleeve portion, made from an insulating plastic material, surrounds the electrode and serves to protect surrounding tissue when the electrode is energized, the delivery of energy thus being confined to the tip that has been inserted into the tissue mass to be ablated. The Examiner acknowledges that Edwards fails to disclose the step of making an incision into the tissue which has been ablated. Applicant agrees. When tissue is ablated it does not necessarily need to be removed and thus Edwards I does not teach making an incision or resecting the tissue as acknowledged by the Examiner. Moreover, Edwards I does not teach

“advancing the applicator along the planned incision line, extending the tissue-piercing distal tips of said array of needles into the volume of tissue to be resected along the planned incision line,” “applying electromagnetic energy three-dimensionally among the array of needles into the volume of tissue,” or “bloodlessly resecting the volume of tissue” as claimed by Applicant in claim 1 or “extending the tissue-piercing means of said array of needles to a desired depth of a volume of the tissue to be treated” and “bloodlessly resecting the tissue from the body” as claimed by Applicant in claim 3.

The Examiner then states that Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss thus suggesting a theoretical combination. However, Swanson discloses a blunt-tipped probe that is placed on or adjacent tissue to deliver energy. See, e.g. FIG. 71A. The probe of Swanson is not advanced into and does not pierce the tissue to be treated. Importantly, Swanson does not disclose resecting tissue along a planned incision line. Swanson teaches away from the present invention by disclosing:

A surgical method in accordance with a present invention may be used to reduce the level of bleeding during surgical procedures. The method generally comprises the steps of coagulating (or ablating) tissue to a predetermined depth and then forming an incision in the coagulated tissue. The coagulation can be accomplished by applying RF energy with, for example, the probe shown in FIG. 71a. Because the tissue is coagulated, the incision will not result in bleeding.

One exemplary procedure employing the present method is the removal of a diseased liver lobe. This [is] a relatively time consuming procedure and, using conventional surgical techniques, there is a significant risk of serious bleeding. In accordance with one embodiment of the present invention, tissue in the lobe is coagulated to a depth of approximately 3 mm to 7 mm using RF energy. The coagulated tissue is then cut and separated with a scalpel, electro-surgical device, or other suitable instrument. To avoid bleeding, the depth of the cut should not exceed the depth of the coagulated tissue. The process of coagulating tissue and then forming an incision in the coagulated tissue can be repeated until the incision reaches the desired depth. Here, each coagulation and incision cycle will take approximately 90 seconds, 60 seconds to perform the coagulation and 30 seconds to perform the incision.

The present surgical technique is, of course, applicable to surgical procedures in addition to the removal of a liver lobe. Such procedures may, for example, involve the spleen, the kidneys, other areas of the liver, the heart, skeletal muscle, the lungs (such as a pulmonary lobotomy) and the brain. The present

technique is also useful in oncological surgical procedures because cancerous tumors tend to be highly vascularized. One exemplary oncological procedure is the de-bulking of a cancerous tumor.

A surgical tool set in accordance with a present invention includes, among the other tools needed for a particular procedure, a device for coagulating soft tissue and a device for cutting the tissue. Suitable devices for coagulating soft tissue are illustrated for example, in FIGS. 62-88 and 95-101. With respect to the probe shown in FIGS. 71f and 71g, the portion of the probe which includes the second connector portion 321, the shaft 310 and a plurality of electrode elements can be included in the tool set with or without the handle 312". As noted above, scalpels (such as the scalpel 375 in FIG. 102), electro-surgical devices and other suitable instruments may be used to cut tissue. Preferably, as illustrated for example in FIG. 102, the tool set is housed in a sterile package 377 that has a flat rigid bottom portion and a top transparent top cover 379 that provides recesses for the tools, thereby providing a ready to use surgical kit. The bottom portion may be formed from TYVEK spun bonded plastic fibers, or other suitable materials, which allow the contents of the package to be sterilized after the tools are sealed within the package.

Col. 45, line 19 to col. 46, line 5

None of the embodiments of probes suggested by Swanson include a probe that pierces tissue for one simple reason, namely advancing tissue-piercing needles into tissue would cause the excessive bleeding that Swanson teaches is desirable to avoid. Therefore, Swanson teaches away from using needles with tissue-piercing means and advancing the tissue-piercing means into tissue as claimed by Applicant in claims 1 and 3. Swanson teaches that resecting tissue must be done by using a blunt probe that is placed on the tissue, not into the tissue and certainly not in tissue-piercing engagement. Because Swanson discourages the modification suggested by the Examiner, Swanson cannot be combined with Edwards. As a consequence, one of ordinary skill in the art would not combine Edwards with Swanson because Swanson teaches that it is not desirable to use needles that pierce tissue.

Even if one skilled in the art modified Swanson with the Edwards device to pierce tissue, the method taught by Swanson would still involve the painstakingly slow process of a probe introduced repeatedly into a depth of tissue over and over again until the desired depth is reached and then moving it along a planned incision line (which is not disclosed in either of Swanson or Edwards). Thus, as with the Edwards devices, the heat pattern from location to location of a modified Swanson device and method would not consistent or uniform and the closing off of the major blood vessels in the liver would not be possible. Therefore, one skilled in the art would

not be motivated to combine Edwards with Swanson. Applicant's novel and unobvious invention inserts needles to a desired depth, applies energy, and moves on to the next location where it again is capable of consistent application of energy in a three-dimensional pattern. It is this quick and reliably consistent three-dimensional application of energy that has made the device claimed by the present invention successful.

Moreover, neither Edwards I, Edwards II, or Swanson alone or in combination teaches that with the three dimensional application of energy, an organ can be bloodlessly resected. In the case of the liver, it is a highly vascularized organ and blood flow to and from it is extremely complex and involves major hepatic arteries and portal veins that are between 10 and 20 mm in diameter. Merely modifying the Swanson device with the Edwards' needles and inserting such a device into the liver would not close off these major blood vessels. Thus, at the time the claimed invention was made, one of ordinary skill in the art would not have recognized that three-dimensional application of energy among an array of needles would effectively close off these major blood vessels and result in a bloodless resection. Therefore, one skilled in the art would not have been motivated to combine the references. The recognition of the invention claimed by independent claims 1 and 3 required more than ordinary creativity.

The theoretical combination of the probe of Edwards I or II with the device of Swanson does not result in the claimed invention. If the probe of Edwards I and/or II were combined with the device of Swanson such a theoretical combination would not result in a probe having an array of needles that surround a volume of tissue and transmit electromagnetic energy three-dimensionally among the array of needles to achieve a bloodless resection.

When a combination of elements yield an unpredictable result, i.e. that the three-dimensional application of energy results in a bloodless resection, the combination is not obvious. In particular, when prior art references teach away from the combination, as does Swanson '760, the discovery of successful means to combine them is more likely to be nonobvious. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d at 1395. Applicant respectfully suggests that claims 1 and 3 are allowable over the art of record and because the dependent claims depend from allowable base claims, Applicant respectfully suggest that they too are allowable.

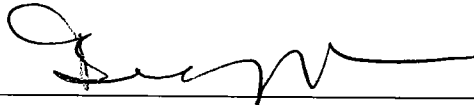
Conclusion

Applicant has made a significant contribution to the art of surgery and allowance of all claims is respectfully requested. If the Examiner believes that a teleconference would be of value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below. Applicant hereby petitions for a two-month extension of time, the statutory period for response having expired on September 12, 2007 and this response being filed on or before the two-month extension period of November 12, 2007. Applicant hereby authorizes the Commissioner to charge the two-month extension of time fee to Deposit Account No. 50-1901 (Reference #22413-14).

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Respectfully submitted,

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